By: Raymond H.B. No. 1545

A BILL TO BE ENTITLED

1	AN ACT
2	relating to a prescription drug purchasing program and an
3	associated assistance program.
4	BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF TEXAS:
5	SECTION 1. Chapter 531, Government Code, is amended by
6	adding Subchapter K to read as follows:
7	SUBCHAPTER K. FAIR MARKET PRESCRIPTION DRUG PRICING AND
8	PRESCRIPTION DRUG ASSISTANCE PROGRAM
9	Sec. 531.401. DEFINITIONS. In this subchapter:
10	(1) "Labeler" means a person that:
11	(A) has a labeler code from the Food and Drug
12	Administration under 21 C.F.R. Section 207.20; and
13	(B) receives prescription drugs from a
14	manufacturer or wholesaler and repackages those drugs for later
15	retail sale.
16	(2) "Manufacturer" means a manufacturer of
17	prescription drugs as defined by 42 U.S.C. Section 1396r-8(k)(5),
18	including a subsidiary or affiliate of a manufacturer.
19	(3) "Publicly funded entity" means an entity funded
20	wholly or partly with state or local government funds. The term
21	includes a public hospital, a hospital district, a community mental
22	health and mental retardation center, and a county providing
23	indigent health care services under Chapter 61, Health and Safety
24	Code.

(4) "Wholesaler" means a person licensed under 1 2 Subchapter I, Chapter 431, Health and Safety Code. Sec. 531.402. NEGOTIATED PRESCRIPTION DRUG REBATES AND 3 4 DISCOUNT PRICES. (a) The commission shall negotiate with manufacturers and labelers to obtain supplemental Medicaid rebates 5 6 or discount prices for prescription drugs sold in this state, including prescription drugs sold to a publicly funded entity. In 7 negotiating terms for rebates, supplemental rebates, or discount 8 prices, the commission shall: 9 (1) attempt to obtain the lowest of the following 10 prices for each unit of a prescription drug: 11 12 (A) the price calculated each quarter under the Medicaid rebate program in accordance with 42 U.S.C. Section 13 14 1396r-8; 15 (B) the price calculated each quarter under 42 U.S.C. Section 256b; 16 17 (C) the lowest price available each quarter to any publicly funded entity; or 18 19 (D) any other price lower than the prices specified by Paragraphs (A), (B), and (C) that the commission may 20 21 obtain through negotiation; and 22 (2) consider any available information on prescription drug prices or discounts. 23 24 (b) A manufacturer or labeler may voluntarily negotiate 25 with the commission and enter into an agreement to provide:

provided under the Medicaid program in excess of the rebates

(1) supplemental rebates for prescription drugs

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- 1 required by 42 U.S.C. Section 1396r-8;
- 2 (2) discount prices for prescription drugs provided
- 3 under the state pharmaceutical assistance program established
- 4 under Section 531.404; or
- 5 (3) discount prices for prescription drugs provided by
- 6 any other publicly funded entity.
- 7 <u>(c) The commission may combine negotiations for the benefit</u>
- 8 of the state pharmaceutical assistance program under Subsection
- 9 (b)(2) with any other state negotiations regarding prescription
- 10 drug prices as necessary to maximize the amount of rebates
- 11 available.
- 12 Sec. 531.403. PRIOR AUTHORIZATION REQUIREMENTS. (a) If
- 13 the commission and a manufacturer or labeler fail to reach an
- 14 agreement on supplemental Medicaid rebates and discount pricing for
- 15 the state pharmaceutical assistance program established under
- 16 Section 531.404 resulting in the availability of prescription drugs
- 17 at prices not more than the lowest price specified by Section
- 18 531.402(a)(1)(A), (B), or (C), the commission shall:
- 19 (1) place the products of the manufacturer or labeler
- 20 on the state's list of products requiring prior authorization under
- 21 the Medicaid program or any other state-funded program; and
- 22 (2) post the name of the manufacturer or labeler on the
- 23 commission's Internet site.
- 24 (b) Placement of products on a prior authorization list in
- 25 accordance with this section must be conducted in a manner that
- 26 complies with 42 U.S.C. Section 1396r-8(d)(5).
- 27 (c) The commission shall distribute to physicians,

- 1 pharmacists, and other health professionals in this state
- 2 information regarding the relative costs of prescription drugs
- 3 provided by manufacturers and labelers who have entered into
- 4 agreements with the commission under this subchapter and
- 5 prescription drugs provided by manufacturers and labelers who have
- 6 not entered into agreements with the commission under this
- 7 subchapter.
- 8 Sec. 531.404. STATE PHARMACEUTICAL ASSISTANCE PROGRAM:
- 9 GENERAL PROVISIONS. (a) The commission shall establish a state
- 10 pharmaceutical assistance program under 42 U.S.C. Section
- 11 1396r-8(c)(1)(C).
- 12 (b) The program shall promote the use of effective drugs by
- 13 providing for the availability of discounted prices to program
- 14 participants for each prescription drug available under the program
- through an agreement under Section 531.402.
- 16 (c) A person is eligible to participate in the program if
- 17 the person is a resident of this state and:
- (1) qualifies for the program under procedures
- 19 established by the commission;
- 20 (2) participates in any health program provided by a
- 21 publicly funded entity; and
- 22 (3) is not covered by an insurance policy or health
- 23 benefit plan, including a Medicare supplement policy or health
- 24 benefit plan, that provides benefits for prescription drugs.
- 25 (d) A program participant is entitled to obtain, from a
- 26 retail pharmacy that voluntarily participates in the program, a
- 27 prescription drug under the program at a price that does not exceed

1 the sum of: 2 (1) the pharmacy's discounted acquisition cost under 3 the program; and 4 (2) a dispensing fee in an amount equal to 105 percent 5 of the dispensing fee paid for providing the drug under the Medicaid 6 program. (e) The commission shall engage in outreach activities to 7 8 publicize the availability of discounted prescription drug prices 9 under the program and to maximize enrollment in the program. The commission shall establish simplified procedures for enrolling 10 11 program participants. 12 Sec. 531.405. PARTICIPATING WHOLESALERS AND RETAIL PHARMACIES. (a) The commission shall contract with each 13 14 wholesaler that: 15 (1) elects to participate in the state pharmaceutical assistance program established under Section 531.404; and 16 17 (2) satisfies the commission's participation 18 requirements. 19 (b) A contract between the commission and a wholesaler must require the wholesaler to: 20 21 (1) provide prescription drugs available through the program to participating retail pharmacies at a price not to exceed 22 23 the sum of: 24 (A) the wholesaler's discounted acquisition cost under the program; and 25 26 (B) a reasonable delivery fee in an amount

negotiated by the wholesaler and the commission, which fee may vary

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- 1 based on the monthly volume of prescription drugs provided by the
- 2 wholesaler and the number of required weekly deliveries;
- 3 (2) meet service levels specified in the contract;
- 4 (3) provide next-day delivery service on all orders
- 5 under the program by participating retail pharmacies;
- 6 (4) provide software and data interface capacity to
- 7 participating retail pharmacies as necessary to enable pharmacies
- 8 to comply with Subsection (d); and
- 9 (5) participate in the program on an ongoing basis for
- 10 the period specified in the contract.
- 11 (c) The commission shall collect utilization information
- 12 from each participating wholesaler as necessary to administer the
- 13 program. The commission shall protect the confidentiality of any
- 14 information obtained by the commission under this subsection that
- is confidential under state or federal law, rule, or regulation.
- 16 (d) The commission by rule shall require a participating
- 17 <u>retail pharmacy to:</u>
- 18 (1) maintain a separate inventory of prescription
- drugs obtained by the pharmacy under the program or segregate those
- 20 drugs from the pharmacy's other prescription drug stock; and
- 21 (2) maintain separate records of acquisition and
- 22 disposition of prescription drugs obtained by the pharmacy under
- 23 the program, and ensure that all computer records regarding those
- 24 drugs are readily available to the commission.
- 25 (e) A participating retail pharmacy or wholesaler may not
- 26 resell or otherwise transfer a prescription drug obtained under the
- 27 program to:

(1) a retail pharmacy that is not participating in the 1 2 program; or 3 (2) a consumer who is not a program participant. 4 (f) If the commission, after notice and opportunity for a hearing, determines that a participating retail pharmacy or 5 6 wholesaler has acted in violation of Subsection (e), the pharmacy or wholesaler is liable to the manufacturer of the prescription 7 8 drug in an amount equal to the difference between: (1) the retail price of the drug at the time of the 9 wrongful resale or transfer; and 10 (2) the price at which the drug was obtained by the 11 12 pharmacy or wholesaler under the program. Sec. 531.406. CERTAIN REBATE DISPUTES OR DISCREPANCIES. 13 (a) A dispute or discrepancy in the amount of a supplemental 14 15 Medicaid rebate negotiated under Section 531.402 must be resolved 16 using the process established in this section. (b) The commission may hire an independent auditor 17 acceptable to all affected parties to perform an audit at the 18 commission's expense if there is a dispute or discrepancy in favor 19 of a manufacturer or labeler relating to the amount rebated for a 20 21 prescription drug provided by the manufacturer or labeler. If the 22 audit does not resolve the dispute or discrepancy, the manufacturer or labeler shall: 23 (1) provide justification for the dispute or 24 25 discrepancy that is satisfactory to the commission; or

(c) A manufacturer or labeler may hire an independent

(2) pay the additional amount due.

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- 1 auditor acceptable to all affected parties to perform an audit at
- 2 the expense of the manufacturer or labeler if there is a dispute or
- 3 discrepancy in favor of this state relating to the amount rebated
- 4 for a prescription drug provided by the manufacturer or labeler. If
- 5 the audit does not resolve the dispute or discrepancy, the
- 6 commission shall:
- 7 (1) provide justification for the dispute or
- 8 discrepancy that is satisfactory to the manufacturer or labeler; or
- 9 (2) refund to the manufacturer or labeler the amount
- 10 <u>due.</u>
- 11 (d) Any party not satisfied with the resolution of a dispute
- or discrepancy in accordance with Subsection (b) or (c) may request
- 13 <u>in writing a hearing before the State Office of Administrative</u>
- 14 Hearings. The party must include supporting documentation with the
- 15 <u>request for a hearing.</u>
- Sec. 531.407. RULEMAKING. The commission may adopt rules
- 17 as necessary to administer this subchapter.
- 18 Sec. 531.408. ANNUAL REPORT. Not later than January 1 of
- 19 each year, the commission shall report to the legislature on the
- 20 commission's activities under this subchapter. The report must
- 21 <u>include the number of persons enrolled in the state pharmaceutical</u>
- 22 <u>assistance program established under Section 531.404 and</u>
- 23 <u>information regarding the financial condition of that program.</u>
- 24 SECTION 2. If before implementing any provision of this Act
- 25 a state agency determines that a waiver or authorization from a
- 26 federal agency is necessary for implementation of that provision,
- 27 the agency affected by the provision shall request the waiver or

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- 1 authorization and may delay implementing that provision until the
- 2 waiver or authorization is granted.
- 3 SECTION 3. (a) The Health and Human Services Commission
- 4 shall implement Sections 531.402 and 531.403, Government Code, as
- 5 added by this Act, not later than January 1, 2004.
- 6 (b) The Health and Human Services Commission shall
- 7 implement the state pharmaceutical assistance program required by
- 8 Sections 531.404 and 531.405 not later than January 1, 2005.
- 9 SECTION 4. This Act takes effect immediately if it receives
- 10 a vote of two-thirds of all the members elected to each house, as
- 11 provided by Section 39, Article III, Texas Constitution. If this
- 12 Act does not receive the vote necessary for immediate effect, this
- 13 Act takes effect September 1, 2003.